DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 25 2006

Ms. Loretta Mooney
Compliance Engineer
Coltene/Whaledent Incorporated
235 Ascot Parkway
Cuyahoga Falls, Ohio 44223-3701

Re: K051660
Trade/Device Name: Dentronix "DDS 7000" Rapid Dry Heat Sterilizer Sterilization
Regulation Number: 21 CFR 880.6870
Regulation Name: Dry Heat Sterilizer
Regulatory Class: II
Product Code: KMH
Dated: June 21, 2005
Received: June 23, 2005

Dear Ms. Mooney:

This letter corrects our substantially equivalent letter of August 4, 2005.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Janette Y. Michaud M.D

Chiu Lin, Ph.D
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K051660

AUG 4 - 2005

coltène whaledent

Premarket Notification [510(k)] Summary

Owner and Contact	**Device Sponsor and Manufacturer:** Coltene/Whaledent, Inc. 235 Ascot Parkway Cuyahoga Falls, Ohio 44223-3701 **Contact Person:** Loretta Mooney 235 Ascot Parkway Cuyahoga Falls, Ohio 44223 330-916-8800 Summary prepared on June 15, 2005
Device	Trade name – Dentronix DDS 7000 Rapid Dry Heat Sterilizer Sterilization System referred to as the "DDS 7000" for the remainder of this document Common name – Dry Heat Table Top Sterilizer Classification name – Sterilizer, Dry Heat
Predicate Device	The Dentronix DDS 7000 Rapid Dry Heat Sterilizer Sterilization System is substantially equivalent to the Dentronix DDS 5000 Dry Heat Sterilization System, referred to as the "DDS 5000" for the remainder of this document, legally marketed per 510(k) K880322. The DDS 7000 utilizes the same accessories used by the predicate device.
General Description	The DDS 7000, like the DDS 5000 is a convective dry heat batch sterilizer capable of sterilizing un-bagged dental instruments and cooling them for immediate use. It is designed for use with a dedicated rack system that provides for uniform loading to achieve optimum load distribution. The DDS 7000 is equipped with a replaceable HEPA filter to comply with ANSI/AAMI ST50: 2004 cooling requirements. The HEPA filter has a filtration efficiency of 99.7% for 0.3-micron particles. The DDS 7000 is a software-controlled device that allows for the user to preprogram options such as display units (Celsius or Fahrenheit), audible alarm enabled/disabled and safety interlock enabled/disabled. The DDS 7000 monitors the entire cycle and will provide diagnostic error codes in the event of any failure or disruption to the sterilization cycle. A printable log is available for the most recently performed cycle that includes pass/fail notification and error codes if applicable

Intended Use	The DDS 7000 is a countertop convective dry heat sterilizer designed for use in Healthcare facilities for the sterilization of un-bagged dental instruments that can withstand exposure temperatures up to 216°C (420° F). There is a single software-controlled cycle that includes a warm-up and cool down phase in addition to the 3-minute sterilization (exposure) phase. Sterilize (exposure) starts when the RTD/control temperature reaches the operating temperature set point of 190°C (374° F). Complete cycle times average 34-44 minutes and are load dependent. The DDS 7000 achieves optimum results by uniform load distribution utilizing a dedicated rack and tray system as detailed below. 1) **Maximum recommended loads for the DDS 7000-115 sterilizer:** a) Maximum load for a four (4)-rack configuration is four (4) plier racks each holding nine (9) orthodontic pliers each for a total of thirty-six (36) pliers. Other maximum load configuration options are: 32 pliers on eight mini vertical racks; or 20 pliers and hand instruments on four Combo Racks **-(OR)-** b) Maximum load for a full tray configuration is one (1) Horizontal Tray each holding up to six (6) orthodontic pliers or up to (12) single-handle hand instruments. Other maximum load combinations include: (5) orthodontic pliers with up to (2) single-handle hand instruments; or (4) orthodontic pliers with up to (4) single-handle hand instruments; or (3) orthodontic pliers with up to (6) single-handle hand instruments; or (2) Orthodontic pliers with up to (8) single-handle hand instruments; or (1) Orthodontic pliers with up to (10) single-handle hand instruments. **-(OR)-** c) Maximum load for the one (1) half tray and two (2) racks is one (1) Half Tray holding three (3) Orthodontic pliers or six (6) single-handle hand instruments in combination with two (2) plier racks capable of holding nine (9) pliers each for a total of eighteen (18) pliers on plier racks. Other maximum load combinations include: (2) orthodontic pliers with up to (2) single-handle hand instruments in combination with two (2) plier racks capable of holding nine (9) pliers each for a total of eighteen (18) pliers on plier racks; or (1) orthodontic pliers with up to (4) single-handle hand instruments in combination with two (2) plier racks capable of holding nine (9) pliers each for a total of eighteen (18) pliers on plier racks.

Technological Characteristics

Characteristic	DDS 5000 / K880322	DDS 7000
Method of organism Destruction	Dry heat (Forced air)	Dry heat (Forced air)
Method of heating	Electric element, mechanical convection	Electric element, mechanical convection
Sterilizing Temperature	375° F	190° C (374° F)
Sterilizing cycle time	6 minute plus warm-up and cool down	3 minute plus warm-up and cool down
Forced Air Cool Down	Yes – time monitored	Yes – temperature monitored
Controlled instrument	Yes, dedicated rack and	Same

	loading	tray system	
	Safety Door Interlock	On 230 V Unit only	Standard on 115 V and 230 V Unit
	Printer/PC COM Port	No	Yes, Allows Cycle log print out of last cycle
	HEPA Filter Air During Cool Down	No	Yes
	Temperature Monitoring	Yes, LCD display	Yes, LED Display
	Process Error Detection	No	Yes, Software monitors all cycle parameters and provides diagnostic error codes and audible alarm
	User Option(s) Interface	No	Yes, options such as units of measure, door lock and use of the audible alarm can be set by the user
	The chamber sizes are similar in size. The DDS 7000 is slightly taller due to the added HEPA filtration system		
Performance Testing	Temperature studies were performed on full, partial and empty chambers. Performance testing of the DDS 7000 was performed using Bacillus atrophaeus spore strips and inoculated tools using the same organism. Half cycle kills result in an overall 12-log reduction of spores and thus produces a 10^{-6} sterility assurance level (SAL). This testing showed that the DDS 7000 is as safe and effective and performs as well if not better than the predicate device (DDS 5000).		
Software Validation	The software was designed and validated to assure that the device is as safe and effective or better than the predicate device (DDS 5000). "General Principles of Software Validation; Final Guidance for Industry" and "FDA Staff and Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices; Final" were used in the development and validation of the device software.		

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Indications for Use

510(k) Number (if known): Unknown
Device Name: Dentronix DDS 7000 Rapid Dry Heat Sterilizer Sterilization System
Indications for Use:
The DDS 7000 is a countertop convective dry heat sterilizer designed for use in Healthcare facilities for the sterilization of un-bagged dental instruments that can withstand exposure temperatures up to 216°C (420° F). There is a single software-controlled cycle that includes a warm-up and cool down phase in addition to the 3-minute sterilization (exposure) phase. Sterilize (exposure) starts when the RTD/control temperature reaches the operating temperature set point of 190°C (374° F). Complete cycle times average 34-44 minutes and are load dependent. The DDS 7000 achieves optimum results by uniform load distribution utilizing a dedicated rack and tray system as detailed below.

1) **Maximum recommended loads validated for the DDS 7000-115 sterilizer:**

   a) Maximum load for a four (4)-rack configuration is four (4) plier racks each holding nine (9) orthodontic pliers each for a total of thirty-six (36) pliers. Other maximum load configuration options are: 32 pliers on eight mini vertical racks; or 20 pliers and hand instruments on four Combo Racks **-(OR)-**

   b) Maximum load for a full tray configuration is one (1) Horizontal Tray each holding up to six (6) orthodontic pliers or up to (12) single-handle hand instruments. Other maximum load combinations include: (5) orthodontic pliers with up to (2) single-handle hand instruments; or (4) orthodontic pliers with up to (4) single-handle hand instruments; or (3) orthodontic pliers with up to (6) single-handle hand instruments; or (2) Orthodontic pliers with up to (8) single-handle hand instruments; or (1) Orthodontic pliers with up to (10) single-handle hand instruments. **-(OR)-**

   c) Maximum load for the one (1) half tray and two (2) racks is one (1) Half Tray holding three (3) Orthodontic pliers or six (6) single-handle hand instruments in combination with two (2) plier racks capable of holding nine (9) pliers each for a total of eighteen (18) pliers on plier racks. Other maximum load combinations include: (2) orthodontic pliers with up to (2) single-handle hand instruments in combination with two (2) plier racks capable of holding nine (9) pliers each for a total of eighteen (18) pliers on plier racks; or (1) orthodontic pliers with up to (4) single-handle hand instruments in combination with two (2) plier racks capable of holding nine (9) pliers each for a total of eighteen (18) pliers on plier racks.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use __x__ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sheila M. Murphey 8/3/05
(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K051460